Fiscal Note for Permanent Rule Changes for North Carolina Division of Public Health
Requires OSBM Review- Seeking Fast-Track Approval

Agency: Dept. Of Health and Human Services, Division of Public Health, Epidemiology Section, Communicable Disease Branch
Contact: Zack Moore, MD, MPH, Public Health Physician II (zack.moore@dhhs.nc.gov, 715-4698)
Carl Williams, DVM, DACVPM, State Public Health Veterinarian, carl.williams@dhhs.nc.gov, 919-733-0391

Rule Citations:
10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS

Purpose of Rule Changes: *10A NCAC 41A .0101 - Reportable Diseases and Conditions*
Make permanent the temporary rule adding MERS and Chikungunya to Reportable Diseases and Conditions

Relevant Statutes: GS 130A-134; 130A-135; 130A-139; 130A-141

State Impact: Yes (minimal opportunity costs)
Local Impact: Yes (minimal opportunity costs)
Substantial Economic Impact: No

Reason for Proposed Amendment:
Middle East respiratory syndrome (MERS) is an emerging infectious disease first identified in September 2012. It is usually associated with respiratory tract infections and is fatal in approximately 1/3 of cases. This disease can spread rapidly if appropriate control measures are not followed.

Chikungunya virus infection was first characterized in Africa in 1952. In December 2013, sustained transmission was identified in the Caribbean Islands and travel associated cases were identified in continental US shortly thereafter. In July 2014 local transmission was identified in Florida. Rapid application of control measures may help limit spread if cases are reported once identified.

It is imperative that public health authorities be rapidly notified when these infections are suspected or confirmed so that appropriate control measures can be implemented to prevent further spread. For this reason, the State Health Director issued a temporary order pursuant to G.S. 130A-141.1 requiring immediate reporting of either condition effective June 23, 2014. An emergency rule was implemented effective on September 2, 2014, followed by a temporary rule that was effective on December 2, 2014. This proposed amendment replaces the temporary rule to require ongoing reporting of MERS and Chikungunya.

Public Health Disease Surveillance

The core mission of the Communicable Disease Branch of the NC Division of Public Health Epidemiology Section is to identify, prevent, and control communicable diseases. Because communicable diseases can have so much impact on the population, the surveillance and control of such diseases is an important part of protecting the public's health. The first step is this process is disease surveillance, which is accomplished by requiring healthcare providers to report diseases and conditions enumerated in the 10A NCAC41A.

"Disease surveillance is the ongoing, systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control. It provides scientific information that used for health action by public health personnel, government leaders, and the public to guide public health policy and programs."(Public Health 101 Series, Introduction to Public Health. Surveillance).

Both MERS and Chikungunya are emerging infectious diseases. Both occur in specific geographic regions (Middle East for MERS and the Caribbean Chikungunyaa) and to date no cases have originated or have transmitted in the United States. By surveilling the diseases, public health monitor the incidence potential spread of the disease to identify any patterns of progression. By observing diseases in their early stages, public health can evaluate the need for potential control measures and then implement these measures before diseases take a foothold. Implementation of early control measures can significantly reduce the burden of disease if let left undetected.

Opportunity Costs

The rule change to require reporting for MERS does not in of itself result in a new impact. The NC State Laboratory for Public Health (SLPH) is the only facility certified to conduct testing for MERS and as a standard of medical care healthcare providers must send samples to the SLPH when conditions indicating MERS present in a patient. Submission of test samples would occur without the rule. Test results from the SLPH are automatically reported to communicable disease staff.

The situation regarding Chinkungya does warrant a fiscal note as testing for this disease is available at other commercial laboratories. Without required reporting, the communicable disease branch would not receive test reports from these other laboratories.

The impact from the required reporting is on communicable disease staff at local health departments, who would now have to expend time reviewing reports for Chikungunya submitted by healthcare providers. The State impact results from additional time that would be required for State communicable disease staff to provide follow-up consultation regarding these test results, and for the SLPH to perform the tests. Further, there is a minimal impact on healthcare providers to report to communicable disease staff. All impacts are minimal opportunity costs involving existing state, local, and private sector staff. No additional expenditures are required.

Table 1 on the following page shows the total estimated impact of this rule change. Figures are based on the total of 89 reports involving Chikungunya during calendar year 2014, and due to the few data points, this fiscal note assumes that the incidence of the disease in the State would stay the same. The fiscal impact on the county agencies was estimated based on mean hourly wage for a Public Health Nurse II, obtained from the Public Health Nursing Program in the NC Division of Public Health. The fiscal impact on the state agency was estimated based on the mean hourly wage for a State Epidemiologist. The fiscal impact on the private sector was estimated based on the amount of time estimated for a healthcare provider staff (usually an RN) to fax medical information to the local health department and/or answer medical questions from the local health department. The wage for this position was obtained from the 2009 State Occupational Employment and Wage Estimates in NC published by the Bureau of Labor Statistics for Registered Nurses.

Table 1

NC DPH Permanent Reporting of Chikungunya

Impact Analysis

Projected Cost Based on Baseline Data from Events Reported in 2014

A. Impact on Private Sector (Based on 20014 Events Reported)

# Events Reported	Total Hours per Event Reported	Hourly Salary of Private Sector Registered Nurse [1]	Total Cost to Private Sector
89	0.5	$40.00	**$1,780**

B. Impact on State Agency: Division of Public Health, Epidemiology Section, Communicable Disease Branch (Based on 20014 Events Reported)

# Events Reported	Total Hours per Event Reported	Hourly Salary of State Epidemiologist [1]	Cost to State Agency
89	1	$90.22	$8,029
# Events Reported	**Total Hours per Event Reported**	**Hourly Salary of Medical Laboratory Technical [1]**	**Cost to State Agency**
89	1	$42.03	$3,741
		Total Cost to State	**$11, 770**

C. Impact on County Agencies: Local Health Department Communicable Disease Branch (Based on 20014 Events Reported)

# Events Reported	Total Hours per Event Reported	Hourly Salary of Public Health Nurse II at LHD [1]	Total Cost to County Agencies
89	1	$30.83	$2,744

D. Total Annual Estimated Economic Impact

Private Costs Sector	$1,780
State / Local Gov't Costs	$14,514
Total Costs	**$16,294**

[1] *Sources for salary data and compensation:*

- Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nc.htm)
- Bureau of Labor Statistics, Employer Costs for Employee Compensation news release, March 11, 2015. http://www.bls.gov/news.release/ecec.nr0.htm

NC Office of State Human Resources. 2014 Compensation & Benefits Report. http://www.oshr.nc.gov/Guide/CompWebSite/2014%20compensation%20&%20benefits%20report.pdf

Appendix A:

CHAPTER 41 - HEALTH: EPIDEMIOLOGY

SUBCHAPTER 41A - COMMUNICABLE DISEASE CONTROL

SECTION .0100 - REPORTING OF COMMUNICABLE DISEASES

10A NCAC 41A .0101 is proposed for amendment as follows:

10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS

(a) The following named diseases and conditions are declared to be dangerous to the public health and are hereby made reportable within the time period specified after the disease or condition is reasonably suspected to exist:

(1) acquired immune deficiency syndrome (AIDS) - 24 hours;

(2) anthrax - immediately;

(3) botulism - immediately;

(4) brucellosis - 7 days;

(5) campylobacter infection - 24 hours;

(6) chancroid - 24 hours;

(7) chikungunya virus infection - 24 hours;

~~(7)~~(8) chlamydial infection (laboratory confirmed) - 7 days;

~~(8)~~(9) cholera - 24 hours;

~~(9)~~(10) Creutzfeldt-Jakob disease – 7 days;

~~(10)~~(11) cryptosporidiosis – 24 hours;

~~(11)~~(12) cyclosporiasis – 24 hours;

~~(12)~~(13) dengue - 7 days;

~~(13)~~(14) diphtheria - 24 hours;

~~(14)~~(15) Escherichia coli, shiga toxin-producing - 24 hours;

~~(15)~~(16) ehrlichiosis – 7 days;

~~(16)~~(17) encephalitis, arboviral - 7 days;

~~(17)~~(18) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes - 24 hours;

~~(18)~~(19) gonorrhea - 24 hours;

~~(19)~~(20) granuloma inguinale - 24 hours;

~~(20)~~(21) Haemophilus influenzae, invasive disease - 24 hours;

~~(21)~~(22) Hantavirus infection – 7 days;

~~(22)~~(23) Hemolytic-uremic syndrome – 24 hours;

~~(23)~~(24) Hemorrhagic fever virus infection – immediately;

~~(24)~~(25) hepatitis A - 24 hours;

~~(25)~~(26) hepatitis B - 24 hours;

~~(26)~~(27) hepatitis B carriage - 7 days;

~~(27)~~(28) hepatitis C, acute – 7 days;

~~(28)~~(29) human immunodeficiency virus (HIV) infection confirmed - 24 hours;

~~(29)~~(30) influenza virus infection causing death – 24 hours;

~~(30)~~(31) legionellosis - 7 days;

~~(31)~~(32) leprosy – 7 days;

~~(32)~~(33) leptospirosis - 7 days;

~~(33)~~(34) listeriosis – 24 hours;

~~(34)~~(35) Lyme disease - 7 days;

~~(35)~~(36) lymphogranuloma venereum - 7 days;

~~(36)~~(37) malaria - 7 days;

~~(37)~~(38) measles (rubeola) - 24 hours;

~~(38)~~(39) meningitis, pneumococcal - 7 days;

~~(39)~~(40) meningococcal disease - 24 hours;

(41) Middle East respiratory syndrome (MERS) - 24 hours;

~~(40)~~(42) monkeypox – 24 hours;

~~(41)~~(43) mumps - 7 days;

~~(42)~~(44) nongonococcal urethritis - 7 days;

~~(43)~~(45) novel influenza virus infection – immediately;

~~(44)~~(46) plague - immediately;

~~(45)~~(47) paralytic poliomyelitis - 24 hours;

~~(46)~~(48) pelvic inflammatory disease – 7 days;

~~(47)~~(49) psittacosis - 7 days;

~~(48)~~(50) Q fever - 7 days;

~~(49)~~(51) rabies, human - 24 hours;

~~(50)~~(52) Rocky Mountain spotted fever - 7 days;

~~(51)~~(53) rubella - 24 hours;

~~(52)~~(54) rubella congenital syndrome - 7 days;

~~(53)~~(55) salmonellosis - 24 hours;

~~(54)~~(56) severe acute respiratory syndrome (SARS) – 24 hours;

~~(55)~~(57) shigellosis - 24 hours;

~~(56)~~(58) smallpox - immediately;

~~(57)~~(59) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;

~~(58)~~(60) streptococcal infection, Group A, invasive disease - 7 days;

~~(59)~~(61) syphilis - 24 hours;

~~(60)~~(62) tetanus - 7 days;

~~(61)~~(63) toxic shock syndrome - 7 days;

~~(62)~~(64) trichinosis - 7 days;

~~(63)~~(65) tuberculosis - 24 hours;

~~(64)~~(66) tularemia – immediately;

~~(65)~~(66) typhoid - 24 hours;

~~(66)~~(67) typhoid carriage (Salmonella typhi) - 7 days;

~~(67)~~(68) typhus, epidemic (louse-borne) - 7 days;

~~(68)~~(69) vaccinia – 24 hours;

~~(69)~~(70) vibrio infection (other than cholera) – 24 hours;

~~(70)~~(71) whooping cough – 24 hours; and

~~(71)~~(72) yellow fever - 7 days.

(b) For purposes of reporting, "confirmed human immunodeficiency virus (HIV) infection" is defined as a positive virus culture, repeatedly reactive EIA antibody test confirmed by western blot or indirect immunofluorescent antibody test, positive nucleic acid detection (NAT) test, or other confirmed testing method approved by the Director of the State Public Health Laboratory conducted on or after February 1, 1990. In selecting additional tests for approval, the Director of the State Public Health Laboratory shall consider whether such tests have been approved by the federal Food and Drug Administration, recommended by the federal Centers for Disease Control and Prevention, and endorsed by the Association of Public Health Laboratories.

(c) In addition to the laboratory reports for Mycobacterium tuberculosis, Neisseria gonorrhoeae, and syphilis specified in G.S. 130A-139, laboratories shall report:

(1) Isolation or other specific identification of the following organisms or their products from human clinical specimens:

(A) Any hantavirus or hemorrhagic fever virus.

(B) Arthropod-borne virus (any type).

(C) Bacillus anthracis, the cause of anthrax.

(D) Bordetella pertussis, the cause of whooping cough (pertussis).

(E) Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).

(F) Brucella spp., the causes of brucellosis.

(G) Campylobacter spp., the causes of campylobacteriosis.

(H) Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.

(I) Clostridium botulinum, a cause of botulism.

(J) Clostridium tetani, the cause of tetanus.

(K) Corynebacterium diphtheriae, the cause of diphtheria.

(L) Coxiella burnetii, the cause of Q fever.

(M) Cryptosporidium parvum, the cause of human cryptosporidiosis.

(N) Cyclospora cayetanesis, the cause of cyclosporiasis.

(O) Ehrlichia spp., the causes of ehrlichiosis.

(P) Shiga toxin-producing Escherichia coli, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.

(Q) Francisella tularensis, the cause of tularemia.

(R) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.

(S) Human Immunodeficiency Virus, the cause of AIDS.

(T) Legionella spp., the causes of legionellosis.

(U) Leptospira spp., the causes of leptospirosis.

(V) Listeria monocytogenes, the cause of listeriosis.

(W) Middle East respiratory syndrome virus.

~~(W)~~(X) Monkeypox.

~~(X)~~(Y) Mycobacterium leprae, the cause of leprosy.

~~(Y)~~(Z) Plasmodium falciparum, P. malariae, P. ovale, and P. vivax, the causes of malaria in humans.

~~(Z)~~(AA) Poliovirus (any), the cause of poliomyelitis.

~~(AA)~~(BB)Rabies virus.

~~(BB)~~(CC)Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.

~~(CC)~~(DD)Rubella virus.

~~(DD)~~(EE)Salmonella spp., the causes of salmonellosis.

~~(EE)~~(FF)Shigella spp., the causes of shigellosis.

~~(FF)~~(GG)Smallpox virus, the cause of smallpox.

~~(GG)~~(HH)Staphylococcus aureus with reduced susceptibility to vanomycin.

~~(HH)~~(II) Trichinella spiralis, the cause of trichinosis.

(~~II~~)(JJ) Vaccinia virus.

~~(JJ)~~(KK) Vibrio spp., the causes of cholera and other vibrioses.

~~(KK)~~(LL)Yellow fever virus.

~~(LL)~~(MM)Yersinia pestis, the cause of plague.

(2) Isolation or other specific identification of the following organisms from normally sterile human body sites:

(A) Group A Streptococcus pyogenes (group A streptococci).

(B) Haemophilus influenzae, serotype b.

(C) Neisseria meningitidis, the cause of meningococcal disease.

(3) Positive serologic test results, as specified, for the following infections:

(A) Fourfold or greater changes or equivalent changes in serum antibody titers to:

(i) Any arthropod-borne viruses associated with meningitis or encephalitis in a human.

(ii) Any hantavirus or hemorrhagic fever virus.

(iii) Chlamydia psittaci, the cause of psittacosis.

(iv) Coxiella burnetii, the cause of Q fever.

(v) Dengue virus.

(vi) Ehrlichia spp., the causes of ehrlichiosis.

(vii) Measles (rubeola) virus.

(viii) Mumps virus.

(ix) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.

(x) Rubella virus.

(xi) Yellow fever virus.

(B) The presence of IgM serum antibodies to:

(i) Chlamydia psittaci.

(ii) Hepatitis A virus.

(iii) Hepatitis B virus core antigen.

(iv) Rubella virus.

(v) Rubeola (measles) virus.

(vi) Yellow fever virus.

(4) Laboratory results from tests to determine the absolute and relative counts for the T-helper (CD4) subset of lymphocytes and all results from tests to determine HIV viral load.

History Note: *Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141;*